4160-01

55FR49644
11-30-90

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

21 CFR PART 820

[DOCKET NO. 90N-0172]

MEDICAL DEVICES; CURRENT GOOD MANUFACTURING PRACTICES (CGMP) REGULATIONS DOCUMENT; SUGGESTED CHANGES; AVAILABILITY

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; availability of document.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an information document created to facilitate the development of changes to the medical devices current good manufacturing practices (CGMP) regulations. The information document is intended to facilitate discussion of suggested changes and to generate comments for consideration by the agency when drafting the language for changing the CGMP regulations.

1-29-91

DATES: Written comments by (insert date 60 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Submit written requests for single copies to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist the division in processing your requests. Submit written comments on the information document to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

90-568 90N-0172

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The information document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

W. Fred Hooten,
Center for Devices and Radiological Health (HFZ-330),
Food and Drug Administration,
1390 Piccard Dr.,
Rockville, MD 20850,
301-427-1131.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of June 15, 1990 (55 FR 24544), FDA published an advance notice of proposed rulemaking. In this notice, the agency announced that it was considering whether changes should be made in the current good manufacturing practices (CGMP) regulations for medical devices (21 CFR Part 820). On June 19 and 20, 1990, FDA presented proposed revisions during an open public meeting of the Device GMP Advisory Committee (the Advisory Committee). At this meeting, FDA promised to seek comments from interested persons in the development of the proposed changes.

The information document made available by this notice is one mechanism the agency is using to meet the committment made during the Advisory Committee meeting. It is intended to facilitate discussion of suggested changes and to generate comments for consideration by the agency when drafting the

language for changing the CGMP regulations. The draft language developed from the comments will then be offered as a proposed rule for comment.

Dated: November 23, 1990.

November 23, 1990

Ronald G. Chesemore
Associate Commissioner for
Regulatory Affairs

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